

REMARKS

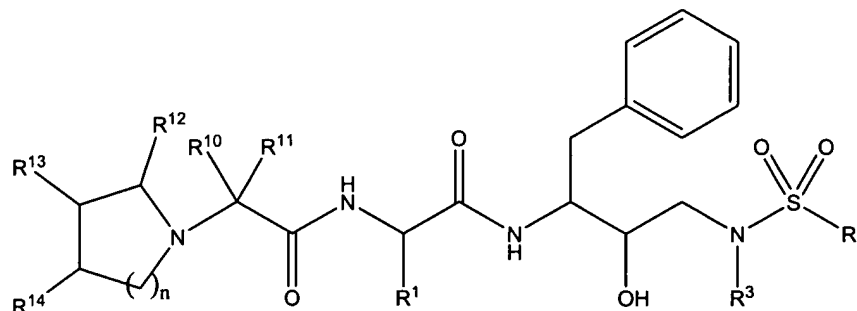
Claims 1-6 and 8-21 are pending in this application. Claim 7 has been canceled without prejudice or disclaimer in the Supplemental Preliminary Amendment filed July 23, 2004.

Restriction Requirement under 35 U.S.C. §121 and Election of Species

i) Election

The Office Action has imposed a restriction requirement between Group I (claims 1-6, 8, 14, 15, 18, and 19, directed to products) and Group II (claims 9-13, 16, 17, 20, and 21, directed to methods of use).

In response, Applicants elect the invention of Group I. Claim 1 of Group I recites a compound represented by the formula:

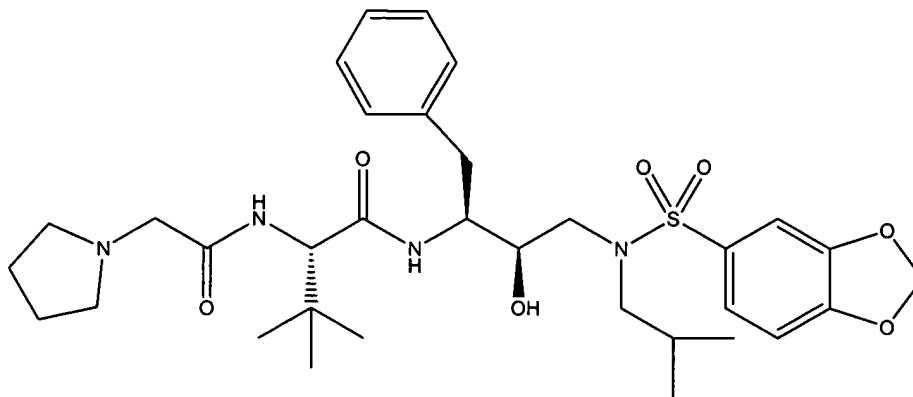


or a pharmaceutically acceptable salt, prodrug or ester thereof, wherein n, R¹, R³, R⁴, and R¹⁰-R¹⁴ are as defined in claim 1.

Applicants hereby elect for examination the species which is the compound:

N-[2R-hydroxy-3-[[1,3-benzodioxol-5-yl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2S-[[pyrrolidin-1-yl)acetyl]amino]-3,3-dimethylbutanamide.

This compound has the structure



and is a compound of claim 1, wherein n is 1; R¹ is t-butyl (an alkyl of 1-5 carbon atoms, as recited); R³ is isobutyl (an alkyl of 1-5 carbon atoms, as recited); R⁴ is 1,3-benzodioxol-5-yl (a benzo fused 5 ring member heterocyclo, as recited); and R¹⁰-R¹⁴ are hydrogen.

The elected species is described in Example 37, at pages 95-99 of the specification, with respect to its synthesis. The elected species is also described in Example 61, at pages 182-184 (see Table 21, first entry), with respect to its measured retroviral protease inhibitory activity (IC₅₀) and biological efficacy (EC₅₀).

All claims of Group I read on this elected species.

The method of use claims 9-13, 16, 17, 20, and 21, by virtue of their dependency on the elected product claims, are of the same scope and therefore comply with the requirements under M.P.E.P. § 821.04 for rejoinder.

ii) Compounds Embracing the Elected Species and within the Same Inventive Concept

The Office Action states

...upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice).

* * *

If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice (emphasis in original).

In response, Applicants respectfully submit that the entire scope compounds embraced by claim 1, is within the same “inventive concept.” This is evidenced by the issuance of related U.S. Patent Nos. 5,756,533; 5,968,970; 5,965,601; 6,310,080; and 6,458,785, having claims of comparable or even broader scope than the now-pending claims of elected Group I. As such, claims 1-6, 8, 14, 15, 18, and 19 are directed to a single invention and should be examined without restriction among Markush group members.

In particular, now that Applicants have complied with the election-of-species requirement, they are entitled to full examination on the merits of claims 1-6, 8, 14, 15, 18, and 19, reading on the elected species. According to MPEP § 803.02, in Markush claim practice,

...the examiner may require a provisional election of a single species prior to examination on the merits. ...Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. (emphasis added).

....
On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a *non-elected species*, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration.

Furthermore, MPEP § 803.02 states, “[I]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention.” (emphasis added). Unity of invention is based on well-settled judicial precedent.

For example, the MPEP cites *In re Harnisch* and *Ex parte Hozumi*. 206 U.S.P.Q. 300 (C.C.P.A. 1980) and 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984). In *Harnisch*, the Court of Customs and Patent Appeals rejected the imposition of a restriction requirement in a Markush-type claim where all of the compounds had a single use, and thus had unity of invention. Likewise, in *Hozumi*, the Board of Patent Appeals and Interferences (hereinafter “Board”) reversed a rejection of a Markush-type claim, where the compounds were core structures having plural diverse pendant moieties.

Other decisions reinforce the proposition that unity of invention is based on a common utility. For example, in *In re Jones*, the Court of Customs and Patent Appeals reversed the Board’s ‘improper Markush group’ rejection precisely because the claimed compounds had a common function. 162 F.2d 479, 74 U.S.P.Q. 149 (C.C.P.A.1947). In *Ex parte Dahlen*, 42 U.S.P.Q. 208 (Bd. App. 1938), the Board permitted claims to compounds having a common core with pendant widely-varying side chains, because the claimed compounds had a community of properties.

Based on the above decisions, claims 1-6, 8, 14, 15, 18, and 19 have unity of invention, because these claims embrace a single inventive concept. The compounds of these claims are retroviral protease inhibitors. These have a single common core and pendant moieties, as set forth in the definitions of n, R¹, R³, R⁴, and R¹⁰-R¹⁴. No matter which combination of pendant moieties is selected, the resulting compound is a retroviral protease inhibitor. Such compounds may also have other uses, but all are retroviral protease inhibitors. To restrict claims 1-6, 8, 14, 15, 18, and 19 to any scope less than their full scope is contrary to established precedent and M.P.E.P. guidance.

CONCLUSION

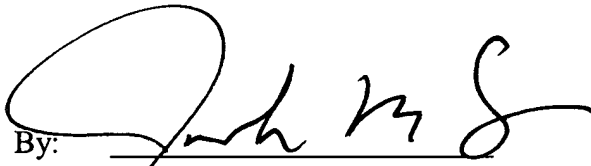
In summary, Applicants have now elected a species, in response the restriction requirement imposed in the Office Action. Established procedures of MPEP § 803.02 require full examination of claims reading on the elected species. Restriction of claims 1-6, 8, 14, 15, 18, and 19 to any scope less than their full scope is improper.

Prompt and favorable consideration of the pending claims is earnestly solicited.

Respectfully submitted,

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